EXBHIBIT A

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PATENT COVER SHEET FOR PROVISIONAL APPLICATION

Docket Number: S85.2-8535			Type a plus sign (+) inside this box ⇒
Inventor(s) / Applicant(s)			
Last Name	First Name	Middle Initial	Residence *(City and State OR City and Foreign Country)*
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☐ Additional inventors are being named on separately numbered sheets attached hereto.

Title of the Invention ***(280 characters maximum)***

ANNULUS-REINFORCING BAND

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State	MN	Zip Code	55343	Country	UNITED STATES OF AMERICA

Enclosed Application Parts ***(check all that apply)***

☒ Specification Number of Pages: 28 ☐ Small Entity
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Method of Payment of Filing Fees For This Provisional Application For Patent ***(check one)***

☒ A check or money order is enclosed to cover the filing fees. ☐ The Commissioner is hereby authorized to charge the filing fees to Deposit Account No. 22-0350. ☒ The Commissioner is hereby authorized to charge any deficiencies or credit any over-payment to Deposit Account No. 22-0350.	Filing Fee Amount(s):	$150.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government: ☒ NO ☐ YES, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,
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PROVISIONAL APPLICATION

DOCKET NO. S85.2C-8535

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

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TITLE:

Annulus-reinforcing Band

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to devices that provide a means to support and/or reinforce and/or stabilize a diseased mammalian spinal intervertebral disc.

Description of the Related Art

It is recognized that the spinal disc consists of three parts: first, the nucleus, a central portion that is a compression-resisting cushion; second, the annulus, a peripheral rim portion that is a tension-resisting hoop; and third, the end plate, the superior and inferior borders of the disc, consisting of the up and down borders of the vertebral body bones.

Many studies have conclude that mechanical back pain is the most common and costly musculoskeletal condition affecting middle-aged humans in modern societies. Mechanical back pain may be caused by several factors, but overwhelming evidence suggests that degeneration of the spinal intervertebral disc, such as may be caused by Degenerative Disc Disease (DDD) is the most common condition causing back pain symptoms.

The inventor, in a previously published work entitled *The tissue origin of low back pain and sciatica: A report of pain response to tissue stimulation during operations on the lumbar spine using local anesthesia*. (Orthop. Clin. North Amer. 1991; 22(2):181-187.), demonstrated that the diseased disc rim or annulus is the principle pain generator responsible for mechanical back pain.

Many devices have been invented for the purpose of stabilizing and/or replacing parts of the disc in an effort to ease the pain associated with disc disease. Indeed, one of the author's prior inventions, the BAK has been used in more than 80,000 humans, with generally good results (See generally: *the Bagby and Kuslich Method of Lumbar Interbody Fusion. History, Techniques, and 2-year Follow-up Results of a United States Prospective, Multicenter Trial.* Kuslich S. D., Ulstrom C. L., Griffith S. L., Ahern J. W., Dowdle J.D., Spine 1998;23:1267-1279; *Summary of Safety and Effectiveness Of the BAK Interbody Fusion System*, Food and Drug Administration (FDA) (PMA 950002), PMA Document Mail Center (HFZ-401), Center for Disease and Radiological Health, Washington DC, September 20, 1996; and *Lumbar Interbody Cage Fusion for Back Pain: an Update on The BAK (Bagby and Kuslich) System*, Kuslich S. D., Spine: State of the Art Reviews 1999;13(2):295-311). Unfortunately, the BAK and many similarly structured rigid metallic implants suffer from several less than ideal features such as: the need to create fairly large surgical exposures, the need for fairly large entrance holes through the annulus of the disc, and the presence of fairly large volumes of metal that reduce surface contact at the end plate.

Any device that would more easily, and/or more effectively, and/or more safely treat degenerative disc disease would be useful in the management of hundreds of thousands of suffering individuals.

Previous patents involving intervertebral devices designed to treat DDD fall generally into the following four classes:

The first class includes rigid, three-dimensional geometric solid devices, either impervious or porous, that function as support struts. When placed in the area of the disc between adjacent vertebral bodies, they allow and/or encourage bone to grow through and/or around the device to cause a bony fusion between two adjacent vertebral bodies. Examples of such devices have been described in the following references:

U.S. 6,015,436 to Schönhöffer
U.S. 6,010,502 to Bagby
U.S. 5,972,031 to Biedermann et al.
U.S. 5,895,427 to Kuslich
U.S. 5,735,899 to Schwartz et al.
U.S. 5,720,748 to Kuslich
U.S. 5,709,683 to Bagby

U.S. 5,700,291 to Kuslich
U.S. 5,669,909 to Zdeblick
U.S. 5,514,180 to Heggeness et al.
U.S. 5,591,235 to Kuslich
U.S. 5,489,308 to Kuslich
U.S. 5,489,307 to Kuslich
U.S. 5,405,391 to Henderson et al.
U.S. 5,263,953 to Bagby
U.S. 5,059,193 to Kuslich
U.S. 5,015,255 to Kuslich
U.S. 5,015,247 to Michelson
U.S. 4,946,458 to Harms et al.
U.S. 4,936,848 to Bagby
U.S. 4,834,757 to Bantigan
U.S. 4,820,305 both to Harms et al.
U.S. 4,501,269 to Bagby
U.S. 4,401,112 to Rezaian

The second class involves the use of semi-rigid artificial joints that allow motion in one or more planes. Examples include U.S. 4,759,769 to Kostuik, U.S. 6,039,763 to Shelokov, and commercially available examples such as the Link device or Charite Intervertebral Disc Endoprosthesis.

The third class is directed to non-rigid cushions designed to replace the nucleus of the disc. Examples of artificial disks are described in U.S. 4,904,260 to Ray, U.S. 4,772,287 to Ray and U.S. 5,192,326 to Boa.

Finally, the fourth class is the relatively new area of initially flexible, expandable bags or balloons that become rigid when injected with materials that can support loads. Examples include U.S. Patents 5,571,189 and 5,549,679 to Kuslich, each of which describe expandable, porous balloons or bags, useful in stabilizing a deteriorating spinal disc. In this fourth class, a porous bag or balloon is used which is closed except for a mouth through which bone graft or other graft material is inserted. The bag is placed into a reamed out intervertebral space and is expanded by the introduction of graft material. Recent research and development in the inventor's laboratory established the fact that a thin walled band or hoop, either porous or non-porous, can be placed in the region of the annulus by means of several techniques. Such a band or bands as described in detail below effectively reinforce the annulus and thereby support spinal motion segment strain deflections resulting from stresses applied in all

vector directions: rotation, flexion-extension, side bending, compression and distraction. Furthermore, the inventor's experiments show that these radially applied bands or hoops can effectively contain and retain inserted or injected materials that are placed in the central region of a reamed-out disc.

The current invention teaches a technique for building and using a simple band to perform many of the functions of the prior art described above. For instance, if compared to metal cylindrical implants such as described in U.S. 5,015,247 to Michelson and metal-walled or plastic-walled rectangular shaped implants such as may be described in U.S. 4,878,915 and U.S. 4,743,256 both to Brantigan, the bands of this invention are softer, lighter, more pliable, and without hard sharp edges, thereby offering greater safety during passage next to delicate structures such as the great vessels or the spinal cord. Also, the completely open structure at the Polar Regions adjacent to cancellous bone of the vertebral bodies, would allow for a more intimate fit between inserted graft material and living bone. This intimacy of contact, without any intervening implant material, may reasonably lead to a faster and more complete biological ingrowth through the central portion of the implant.

It is well known that greater surface area contact between graft and living bone is conducive to higher fusion rates and conversely, lower non-union rates. Thus, the current invention provides for several unique advantages over prior art in the field of interbody fusion devices.

In addition to its uses and advantages in the form of an improved interbody fusion devices, the attributes of the current invention would provide a new and potentially superior technology in two other categories of treatment for degenerative disc disease: one, soft tissue reinforcement of diseased discs, and two, disc replacement.

In regard to soft tissue reinforcement of diseased disks, several new techniques have recently become available to treat early and mid-stage disc degeneration by methods less invasive and less drastic than fusion surgery. Examples include: annular tissue modulation by heat application (See generally: Saal J. et al. North American Spine Society presentations 1999, 2000); the use of a polyester tension band placed around and between pedicle screws above and below the involved disc such as, described in U.S. 5,092,266 to Graf; and combined tension and distraction devices placed between pedicle

screws, such as may be seen in the commercially available Dynesys™ device from Sulzer Orthopedics Ltd. While early results from the above technologies appear promising, the current invention would obviate some of the potential dangers and drawbacks of these systems. For example:

In the case of annular tissue modulation by heat application, the current invention does not require heat. Heat can be injurious to local spinal nerves and vessels, possibly leading the paralysis or even death by hemorrhage. The current invention immediately stabilizes the annulus, rather than having to wait until the heat-damaged tissue heals and shrinks.

In the case of polymeric tension band placed between pedicle screws above and below the involved disc, the current invention does not require the placement of pedicle screws. The placement of pedicle screws requires a significant surgical exposure with attendant bleeding and injury to local muscular, ligamentous, vascular and nervous tissues. The current invention can be installed through much smaller, microsurgical exposures that would have less likelihood of causing collateral damage.

In the case of combined tension and distraction devices placed between pedicle screws, the current invention directly stabilizes the very tissue that is causing the discogenic pain the annulus, rather than attempting to stabilize the annulus by an external, cantilevered system that has all of the risks and disadvantages of the use polyester tension bands and pedicle screws

The current invention is a basic departure from the prior art at a very fundamental level. The core element of the invention is the simple but broad concept of applying a tension-resisting circumferential band at or near the mid or outer circumference of the annulus. A careful review of the patent and medical literature and prior art did not provide an instance of this fundamental concept having been previously described. Once conceived, the core idea of using a circumferential tension band to reinforce an injured disc annulus led to a number of alternative embodiments, spanning the treatment options all the way from simple reinforcement, to containment of graft material for interbody fusion, to radial containment of a centrally placed compressible or incompressible nuclear replacement material. In other words, the basic concept of the current invention could provide the critical element that would allow a developer and/or

a surgeon a new means to structure a new and potentially better annular support for a less invasive early to mid-stage degenerative disc disease treatment method. The invention would also provide an improved means of graft support for a less invasive interbody fusion method. Finally, the invention would provide an improved means of support for nuclear material (biological or non-biological, bioactive or inert, hydrophilic or non-hydrophilic, granular or amorphous) - for nuclear replacement or so-called artificial disc replacement.

The entire content of each and all patents, patent applications, articles and additional references, mentioned herein, are respectively incorporated in their entirety herein by reference.

The art described in this section is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" with respect to this invention, unless specifically designated as such. In addition, this section should not be construed to mean that a search has been made or that no other pertinent information as defined in 37 C.F.R. § 1.56(a) exists.

BRIEF SUMMARY OF THE INVENTION

The invention provides for an expandable tubular member or band which has side walls and may include a fill opening. However, the expandable band does not require either a bottom or a top as it has been found that a suitable enclosure is created by placing such a band within a reamed out intervertebral space. Pressure within the interior of the band is exerted primarily against the side walls and the adjacent vertebrae surfaces. The pressure exerted by the bone graft material at the top and bottom is exerted against the exposed bone of the adjacent vertebrae which encourages bone growth through the band interior. The bone graft material is contained within the tube by a combination of the natural bony top and bottom together with the sidewall of the band.

The current invention provides a novel means to support the diseased and/or weakened annulus of the disc. This support would offer improved resistance to stresses placed on the spine and therefore would reasonably result in decreased pain and improved function to any individual suffering from the degenerated disc disease condition.

In addition to simply reinforcing the diseased annulus of the disc, the devices based on the invention herein described could also provide a means to retain and contain materials that might be inserted or injected into the disc in an attempt to heal the annulus, to replace the natural nucleus, or to create a bony fusion between the two adjacent vertebral bodies.

In at least one embodiment of the invention, the invention provides a flexible implant that may be inserted into a cavity formed in a degenerating disc. The flexibility of the band allows it to be inserted through a relatively small opening in a disc or vertebra space. The band is then positioned so its fill opening, if any, may receive biological fill material. This material is packed into the flexible bag, causing the band to expand and conform to the cavity formed in the disc or vertebrae. Fill material is added until enough material is present to expand the disc to the desired position. At this time, the band fill opening is closed to prevent egress of the fill material.

In at least one embodiment of the invention, the invention provides for pliable band or hoop that is flexible to normal handling, but cannot stretch circumferentially once it has reached the limits of its circumferential length. The band may have a structural portal to be used for filling, or it may simply be constructed of a fabric-like material that allows a fill tube to perforate its walls to allow for filling. In the latter case, the perforated wall tends to self-seal once the fill tube is withdrawn. The band may be flat or tubular in cross-section. However, unlike a balloon, the band does not require either a bottom or a top, as we found that a top and bottom are unnecessary when using a band or hoop to enclose material injected into a reamed out intervertebral space.

As long as the width of the band is approximately equal to the annulus height (or stated another way, the distance from one vertebral peripheral end-plate to its neighbor) the band serves well to contain particulate material inserted into the center of the disc cavity, without the need for a complete spherical enclosure, as would be provided by a balloon. Since in the case of the reamed out interdiscal cavity, the top opening and bottom opening of the band would be covered by dense vertebral bone, it is not necessary to enclose inserted particulate graft or other material in these regions.

Pressure within the cavity, as would occur when a surgeon injects material into its central region interior to the band, is exerted radially against the band

and the adjacent vertebrae surfaces. As the internal cavity is filled with incompressible material, such as bone graft or bioceramic beads or granules, radial displacement beyond the circumference of the band is restricted. Therefore, any additional injected material would be directed north and south against the vertebral bodies. This action would increase the distance between the vertebral bodies, and produce a so-called disc distraction. This distraction is known to have three salutary results. First, it stabilizes the motion segment by tightening the ligamentous structures. Second, it opens the exiting holes for spinal nerves -the so-called neural foramina- and thus relieves certain types of nerve compression disorders. Third, this improved stability is necessary to allow for bony ingrowth and through-growth, to produce an interbody fusion. The pressure exerted by the bone graft material at the top and bottom is directed against the exposed bone of the adjacent vertebra. This produces an intimate contact that encourages bone growth through the interior of the cavity.

In at least one embodiment, the invention consists of any continuous band or ring that would be placed around and near the outer margin of the intervertebral disc. A suture or preferably a flattened, braided or woven strand or cord, for instance, that was placed circumferentially about a disc and tied to make a tension-resisting ring, would qualify. Modern endoscopic surgical tools, combined with sophisticated surgical navigation systems make this option more practical and safer than would have been possible a few years ago.

In yet another embodiment, the band would be pre-formed to match the anatomy of the patient. It would also be available in a variety of circumferences, plies, thicknesses, widths (in the superior-inferior dimensions), weave patterns, materials and filament diameters. The band would be flexible enough to fit through a small hole made in the annulus, such as during a routine disc hernia removal operation. After removal of the disc hernia, the surgeon would introduce an expandable reamer and thereby remove the degenerated nucleus, the cartilage end plate, and the inner annulus, leaving the outer annulus intact. Examples of such a procedure and expandable reamers are described in U.S. 5,445,639 to Kuslich et al. and co-pending U.S. Pat. App. 60/182,610 to Kuslich et al., filed February 15, 2000, the entire contents of both being incorporated herein by reference.

The properly sized band would be pushed through the disc portal, whereupon, owing to its inherent springiness, or as a result of material being injected in the interior of the disc, the hoop or band would expand radially against the outer annulus. Perforating the mesh fabric of the band, by means of pointed fill tube, would allow the surgeon to fill the cavity with significant pressure using graft material; perhaps by the use of a graft injection system such as described in a co-pending U.S. Patent Application entitled *Tool to Direct Bone Replacement Material,* to Kuslich et al., and is filed concurrently herewith and is a continuation in part application of U.S. Pat. App 09/608,079 the entire contents of the concurrently filed application as well as the 09/608,079 application being incorporated herein by reference. The resulting compressed graft, held from further expansion by the vertebral bone above and below, and the band or hoop radially, would change phase from liquid-like to solid-like, as is known to occur when granular materials are subjected to compression loading (See: *Friction in Granular Flows*, by H.M. Jaeger, Chu-heng Liu, S.R. Nagel and T.A. Witten, Europhysics Lett. 11, 619 (1990); *Granular Solids, Liquids, and Gases*, by H.M. Jaeger, S.R. Nagel and R.P. Behringer, Rev. Mod. Phys. 68, 1259 (1996); and *IUTAM Symposium on Segregation in Granular Flows (Solid Mechanics and its Applications)*, Vol. 81, October 2000). This phase change which has been observed and scientifically characterized by our laboratory experiments and by the work described in U.S. 5,331,975 to Bonutti (see also *Formation of Structural Grafts From Cancellous Bone Fragment*, by P.M. Bonutti, M.J. Cremens, and B.J. Miller, Am. J. Ortop. July 27, 1998: 499-502); each of the above references being incorporated in their entirety herein by reference. This phase change would result in a construct that is capable of both stabilizing the motion segment in the short run, and would foster the development of a solid bony fusion over the long run.

To state the process in another way: the invention provides a pliable implant that may be inserted into a cavity formed in a degenerating disc. The flexibility of the band allows it to be inserted through a relatively small opening in a disc or vertebra space. The band is then positioned so its fill opening may receive fill material. This material is packed into the region interior to the band, causing the band to expand and conform to the cavity formed in the disc or vertebrae. Fill material is added until

enough material is present to expand the disc to the desired position. At this time, the band fill opening is closed, or allowed to self-seal to prevent egress of the fill material.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of the invention is hereafter described with specific reference being made to the drawings in which:

FIG. 1 is a perspective view of a first embodiment of the invention;

FIG. 2 is a top view of the embodiment of FIG. 1;

FIG. 3 is a side view of the embodiment of FIG. 1;

FIG. 4 is a perspective view of an embodiment of the invention having an elongate fill opening;

FIG. 5 is a perspective view of an embodiment of the invention as it may appear when used to replace a spinal disk;

FIG. 6 is a perspective view of an embodiment of the invention wherein the band is a molded material;

FIG. 7 is a side view of an embodiment of the invention shown in the reduced state within a storage/delivery tool;

FIG. 8 is a side view of the embodiment shown in FIG. 7 wherein the inventive band is being removed from the storage/delivery tool;

FIG. 9 is a perspective view of an embodiment of the invention wherein the inventive band has a woven, double walled configuration;

FIG. 10 is a perspective cut away view of the embodiment shown in FIG 9;

FIG. 11 is a perspective view of the embodiment of the invention shown in FIG. 9 wherein the inventive band further includes latitudinally oriented support bands;

FIG. 12 is a perspective cut away view of the embodiment shown in FIG. 11;

FIG. 13 is a perspective view of the embodiment of the invention shown in FIG. 11 wherein the inventive band further includes longitudinally oriented support bands;

FIG. 14 is a perspective cut away view of the embodiment shown in FIG. 13;

FIG. 15 is a side view of an embodiment of the invention wherein the inventive band has a single walled configuration;

FIG. 16 is a perspective view of an embodiment of the invention;

FIG. 17 is a top down view of an embodiment of the invention;

FIG. 18 is a side view of the embodiment of the invention shown in FIG. 15 wherein the inventive band is shown is a partially reduced state;

FIG. 19 is a perspective view of a graft insertion tool suitable for use with the inventive band;

FIG. 20 is a side view of the tool shown in FIG. 19;

FIG. 21 is a top down view of the tool of FIG. 19;

FIG. 22 is a side view of the tool of FIG. 19 seen dislocating the fibers of an embodiment of the inventive band; and

FIG. 23 is a top down cut away view of the tool of FIG. 19 as may be seen during graft insertion.

DETAILED DESCRIPTION OF THE INVENTION

This invention may be characterized as an improvement of the inventor's inventions described in U.S. Patents 5,571,189 and 5,549,679, the disclosures of which are incorporated herein by reference.

With reference to the Figures, FIGs. 1-3 illustrates an embodiment of the inventive implant 10 which consists of a sidewall band 12, which may be characterized as being substantially tubular or ring like in shape. Preferably the band 12 is circular, however elliptical shapes and other geometric shapes may be used.

The band 12 is pliable and malleable before its interior space 14 (not shown in FIG. 2) is filled with the contents to be described. While in this initial condition, the band 12 may be passed, in a collapsed state, through a relatively small tube or portal, such as recited in U.S. Patents 5,571,189 and 5,549,679. This feature is important because access to the intervertebral disc is limited by anatomy and therefore safety considerations direct us to use the smallest possible portal of entry.

The band 12 may be constructed in a variety of ways. The band material 16 may be etched, woven or braided material such as a weave of NITINOL fibers, or a form-molded material such is shown in FIG. 6. The material 16 may be fluid impermeable or may be provided with a density that will allow ingress and egress of fluids and solutions and will allow the ingrowth and through-growth of blood vessels and fibrous tissue and bony trabeculae. Where the material 16 is provided with such a porous construction, pores or weave is preferably tight enough to retain small particles of enclosed material, such as ground up bone graft, other tissues or solid pieces of bone inducing material such as hydroxyapatite or other biocompatible materials known to promote bone formation.

Where the material is porous, such as in the embodiment shown in FIGs. 1-4, the pores or openings 18 of the fabric will have a diameter of about 0.25 mm to about 5.0 mm. The size is selected to allow tissue ingrowth while containing the material packed into the bag.

The material 16 of the invention must be flexible enough to allow it to be collapsed and inserted into an opening smaller than the expanded band size. As may be seen in FIGs. 7 and 8, the band 12 is sufficiently flexible so that it may be positioned into a holding chamber 50 of a storage tube or delivery device 52. Depending on the exact construction of the band 12, the band may be compacted into a substantially smaller configuration than the band is capable of attaining when packed with graft material. The delivery device however, is sized such that the device 52 may be inserted into a surgical opening wherein the band 12 is drawn or pushed by plunger 56 out of the chamber 50, as indicated by the direction of the arrow 54 as shown in FIG. 8, and inserted into a small hole of the annulus 21 of a vetebral disk 23 as may be seen in FIG. 5. Alternatively, the band 12 may be inserted between vertebra when used to replace the entire disk, or within a hollowed space of a vetebral body. However, in order to ensure that the supportive quality of the band 12 is maintained, the material is preferably minimally elastic if at all.

Accordingly, the fabric band 12 may be formed from a polymeric material to which a plurality of perforations are formed or added. It need not be woven and may be molded, such as the embodiment shown in FIG. 6, or otherwise formed as is well known in the art. The preferred material may provide the ability to tailor bioabsorbance

rates. Any suture-type material used medically may be used to form the band 12. The band 12 may be formed of plastic or even metal. The band 12 could be formed from a solid material. The band 12 may be partially or totally absorbable, metal, plastic, woven, solid, film or an extruded balloon.

Preferably the material 16 is light, biocompatible, flexible and easily handled, but is also very strong in terms of resisting tension, and thus unlikely to rip or tear during insertion and expansion. When the device is expanded through insertion of fill material, the device expands to a predetermined shape, and in doing so, it fills a previously excavated space 20 between the vertebral bodies and/or within a vertebral body, such as may be seen in FIG. 5. This filling results in the separation of the vertebral bodies 24 and results in the stabilization of the spinal motion segment, indicated generally at 22.

As may be seen in FIGs. 1-2, and 4-5, the band 12 may be characterized as having two ends 30 and 32. One or both ends 30 and 32 may be open as defined by the band 12. As may be seen in FIG. 5, where the band 12 is utilized to replace a disk, the openings 30 and 32 are characterized as being less than the diameter of the surrounding vertebral bone, thus assuring containment of the graft material within the confines of the interior 14 of the band 12. Where only a single end 30 or 32 is open, the material 16 which covers one or more of the openings is porous to allow for bone growth therethrough such as has been described above.

In addition the band 12 may be equipped with a fill opening 26. The fill opening 26 must be large enough to accommodate passage of fill material as well as the means of placing fill material into the interior space 14 of the band 12. A device which may be suitable for passing through the fill opening 26 for insertion of fill material is described in co-pending U.S. Pat. App. 09/608,079 as discussed above.

Preferably the opening 26 includes a means of preventing passage of fill material out of the interior space 14. In the embodiment shown in FIG. 4, the opening 26 includes an elongate passage 28 which may be tied off or otherwise sealed subsequent to insertion of the fill material.

As may be seen in FIG. 5 when the band 12 is inserted between two vertebra 24 or within a disk or other hollowed region of an intervertebral space and filled

with fill material, the fill material will push against the vertebra surfaces 40 which are adjacent to the top 30 and bottom 32 of the band 12. The band 12 in combination with the vertebra surfaces 40 will contain the fill material within the interior space 14.

In the embodiment of the invention wherein the band material 16 is woven from one or more fibers, the fibers may be composed of a variety of materials as previously discussed. In the various embodiments shown in FIGs. 9-18, the band 12 is constructed from one or more NITINOL fibers 58 which have been woven or braided together into the desired band shape. The use of a shape-memory material such as NITINOL provides the band with sufficient mechanical strength to resist stretching or expansion as a result of the build up of graft material in the interior 14. In addition such shape-memory materials allow the band to be collapsed prior to insertion, such as may be seen in FIGs. 7 an 8 yet which will tend to reacquire its original shape once implanted.

FIGs. 9-18 depict a wide variety of band configurations. As may be seen in FIGs. 9-14 the band 12 may be characterized as a double walled band or a loop of material folded back upon itself. Such a double walled configuration may be seen as having a inner wall 60 which is continuous with the outer wall 62 and defining a toroid shaped space 63 therebetween.

The toroid shaped space 63 may be filled, in whole or in part with pharmaceuticals for drug delivery to the implantation site. The toroid space 63 may also be filled, subsequent to implantation into a vertebral body with a biocompatible cement or other material for providing the band 12 with additional support.

The double walled construction may provide the band 12 with increased strength to provide additional mechanical support for the graft material contained in the interior 14. In addition, the double walled construction may be configured to allow the various openings 18 of the respective walls 60 and 62 to partially overlap. As a result the fibers 58 of one wall, for example inner wall 60, may over lap the openings 18 of the other wall, for example outer wall 62, thereby effectively reducing the size of the openings 18. As a result, a band 12 having a double walled construction may not require any more fibers 58 than a single walled band such as may be seen in FIGs. 15-18. However, it may be desirable to provide a double walled band 12 with a denser weave of fibers 58 for the purpose of providing the band 12 with greater mechanical strength.

Turning to FIGs. 11 and 12, a double walled band 12 may also include one or more latitudinally disposed support members such as members 64 and 66 shown. The individual support members 64 and 66 may be positioned in any manner around the circumference of the band 12. In the embodiment shown, the members 64 and 66 are respectively disposed the first or top opening 30 and the second or bottom opening 32. In addition the members 64 and 66 are located between the inner wall 60 and outer wall 62. The members 64 and 66 may be used to support the material 16 of the band by weaving the fibers 58 about the members 64 and 66, such as may best be seen in FIG. 12.

The members 64 and 66 may be constructed from the same or different material as fibers 58. In addition, the members 64 and 66 may be one or more wires or fibers woven or braided together and oriented in the latitudinal orientation shown. Alternatively, one or more fibers may be equatorially oriented, or may be otherwise positioned anywhere around the circumference of the band 12.

In addition to providing the band 12 with one or more latitudinally oriented wires or members 64 and 66, the band may also include one or more longitudinally oriented members 68 such as may be seen in the embodiment shown in FIGs. 13 and 14. In the embodiment shown, the longitudinal members 68 vertically cross the band 12 to join the latitudinal members 64 and 66. In addition, the latitudinal members 68 are oriented substantially perpendicular to the latitudinal members 64 and 66. The latitudinal members 68 provide the band with compression support relative to the surrounding vertebra. The members 68 may be woven into the fibers 58 or may be independent of the band's woven configuration. In one embodiment where the band is equipped with longitudinal members 68 as well as latitudinal members 64 and 66, the various members may act as a frame work which supports the woven fibers 58 of the band 12.

As with the latitudinal members 64 and 66, the longitudinal members may be constructed out of any suitable material. Such material may be different from or the same as the fibers 58. Additionally, the members 68 may be characterized as one or more fibers 58 oriented in the longitudinal direction shown.

In the various embodiments shown in FIGs. 15-18 it may be seen that the band 12, may be provided with only a single wall construction as opposed to the double

walled construction previously described. As may be seen in FIG. 15, because the single wall 70 is not a continuous overlapping loop of material such as may be seen in FIGs. 9 and 10, the single walled band 12 shown in FIG. 15 may have openings 30 and 32 which have fairly jagged or non-uniform edges 72. While the material 16 of the band 12 may not necessarily be of sufficient hardness to penetrate the surrounding vertebral bone, the non-uniform nature of the edges 72 of the band 12, provides the band 12 with surfaces which may tend to more readily engage the surfaces of the surrounding vertebral bone, thereby preventing the band 12 from shifting or otherwise moving during the graft injection process or thereafter.

As may be seen in FIGs. 15 and 16 the single walled band 12 may be configured to have an essentially cylindrical shape. The cylindrical shape may be compressed into an elongated band such as may be seen in FIGs. 7 an 8 prior to insertion into the body. However, the band 12 may be configured to include other shapes, notably the rounded configuration shown in FIG. 17, when the band 12 is inserted into a vetebral body. As may be seen in FIG. 19, the compactability of a single walled band is illustrated. As with all embodiments of the present invention, the band 12 may be significantly distorted, collapsed or otherwise manipulated in order to collapse the band into a reduced configuration such as may be seen in FIGs. 7 and 8. The present invention may be distorted in either or both the radial and longitudinal directions while retaining its ability to expand subsequent to insertion into the spinal area.

As shown in FIG. 22 and 23, the band 12 is shown with a fill insertion tool 100 being inserted into the interior 14 of the band 12 by passing through one of the spaces or pores 18. The shape of the tool 100 as may best be seen in FIGs. 19-21 is essentially an elongate shaft 104 having a tapered or pointed distal end 102.

Turning to FIGs. 19-21 the fill insertion tool which is suitable for use in the various embodiments of the invention is illustrated. The tool 100 is disclosed in a co-pending U.S. Patent Application entitled *Tool to Direct Bone Replacement Material,* to Kuslich et al., and is filed concurrently herewith and is a continuation in part application of U.S. Pat. App 09/608,079, discussed above. The entire contents of the aforementioned concurrently filed application, and the 09/608,079 parent application being incorporated herein by reference.

The tapered distal end 102 of the tool 100 is sized to enlarge the opening 18 to allow passage of the tool 100 into the interior 14 by pushing aside the various fibers 58 as may best be seen in FIG. 22. The fibers 58 are disposed to open the pore 18 from its nominal diameter of 0.25 to 5 mm to an enlarged opening sufficient to allow passage of a portion of the shaft 104 therethrough.

The extent of tool penetration into the band interior 14 must be sufficient to allow the side opening 106 to be fully contained within the band interior 14. The tool 100 may include more than 1 side opening 106.

As shown in FIG. 23, the side opening 106 allows insertion of the bone graft or other types of fill material 108 into the band interior 12. The tool 100 includes a piston plunger or other means (not shown) for pushing fill material 108 from within the shaft 104, through the side opening 106 and into the band interior 14.

If the internal diameter of the shaft 104 may be about 1.5 mm to 5 mm and is preferably approximately 2.5 mm in diameter. The length of the side opening 106 is preferably between about 1 ½ to 3 times the internal diameter of the shaft 104.

The distal end 102 of the tool 100 is preferably angled to direct the flow and to break down any material that has packed back into more discrete pieces.

While this invention may be embodied in many different forms, there are shown in the drawings and described in detail herein specific preferred embodiments of the invention. The present disclosure is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

This completes the description of the preferred and alternate embodiments of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

CLAIMS

1. A device for stabilizing a spinal motion segment comprising:

a generally pliable, but minimally elastic hoop or band having a central north-south axis, an interior space, and a body at its circumference or equator and sized to fit in the immediate vicinity of the outer annulus of the intervertebral disc of a mammalian spine, the body having a height and thickness and a physical structure.

2. The device of claim 1 wherein the north-south central axis of the hoop or band is intended to be generally collinear with the longitudinal axis, otherwise known as the cephalo-caudal axis, of the mammalian spine.

3. The device of claim 1 wherein the height of the body of the hoop or band, measured in the cephalo-caudal axis, is between 0.25 mm and 20 mm.

4. The device of claim 1 wherein the thickness of the body of the hoop or band is between 0.01 mm and 5 mm.

5. The device of claim 1 wherein the physical structure of the body of the hoop or band is non-porous.

6. The device of claim 1 wherein the physical structure of the body of the hoop or band is porous.

7. The device of claim 1 wherein the physical structure of the body of the hoop or band is capable of conducting electricity.

8. The device of claim 1 wherein the physical structure of the body of the hoop or band is a flattened or unflattened tube.

9. The device of claim 1 wherein the physical structure of the body of the hoop or band is sufficiently deformable or sufficiently pliable to allow its temporary deformation

into an elongated loop, such that the band or hoop may be passed through an opening in the annulus of a mammalian disc whose said opening diameter is generally equivalent to the height of the body of the band or hoop.

10. The device of claim 1 wherein the physical structure of the body of the hoop or band is constructed of a springy material, such that when placed within the interdiscal cavity of a reamed out mammalian disc, the hoop or band expands itself radially into a generally circular or elliptical shape, against the annulus of the disc.

11. The device of claim 1 wherein the springy material is comprised at least partially of NITINOL wire.

12. The device of claim 1 wherein the physical structure of the body of the hoop or band is comprised of at least one of the following configurations: braided filaments, woven filaments, threads, cords, wires, ropes, suture materials, and any combinations thereof.

13. The device of claim 1 wherein the physical structure of the body of the hoop or band is a polymeric material or a cement that hardens after injection to form the main body of the hoop or band.

14. A device comprising a hoop or band, the hoop or band comprising a generally circular or generally elliptical shape when fully extended out from its central axis, the hoop or band constructed and arranged to be placed in the immediate vicinity of the outer annulus of the intervertebral disc of a mammalian spine.

15. A device comprising a generally flexible band-like member sized to fit and expand transversely into a hollowed region of an intervertebral space, the band-like member comprising an interior space, the interior space extending from a first end to a second end, at least one end defining an opening, the opening in fluid communication with the interior space, the band-like member constructed and arranged to expand from a

reduced state to an expanded state by the introduction of fill material into the interior space, the band-like member including at least one fill opening or potential fill opening, through which the fill material may be introduced into the interior space.

16. A device comprising a band having a proximal and a distal end, the band constructed and arranged to be placed into the outer portion of the annulus of a mammalian disc, from a point of entry on the circumference of the annulus, and running generally around the outer annulus, or through or interior to the circumference of the outer annulus, or on the interior border of the disc annulus, returning to an exit point that is generally near to the entrance point, and is then tied or otherwise secured to the portion of the band that lies near its entrance point, the band being tightened to some extent before tying or securing the proximal to the distal end.

17. A device comprising a generally hollow, flattened or unflattened, flexible tubular member sized to fit into a hollowed region of an intervertebral space, the tubular member comprising an interior space, the interior space extending from a first end to a second end, at least one end defining an opening, the opening in fluid communication with the interior space, the tubular member further constructed and arranged to expand from a reduced state to an expanded state by the introduction of fill material into the interior space, the tubular member including at least one fill opening through which the fill material may be introduced into the interior space, the at least one fill opening constructed and arranged to prevent egress of the fill material from the interior space.

18. The device of claim 1 wherein the physical structure of the body of the flexible hoop or band member further comprises a plurality of pores, the plurality of pores being sized to allow ingress and egress of any of the following materials: liquids, solutions, small particle suspensions, and any combinations thereof, the plurality of pores constructed and arranged to allow and ingrowth of bony trabeculae or fibrous elements into and through the device when the device is positioned in a hollowed region of an intervertebral space, the plurality of pores being sized to retain the fill material within the interior space of the tubular member.

19. The device of claim 1 wherein the interior space is intended to lie within the hollowed region of the central portion of an intervertebral space, and the said interior space is defined by adjacent vertebrae above and below, and the remaining annulus peripherally.

20. The device of claim 1 wherein the hollowed region of an intervertebral space is defined by a bored out region of a disk, the device being inserted within the bored out region of the disk in the reduced state.

21. The device of claim 8 wherein the tubular member is composed of a polymeric material.

22. The device of claim 8 wherein the tubular member is composed of a metal wire.

23. The device of claim 8 wherein the tubular member is composed of a woven or braided material.

24. The device of claim 8 wherein the tubular member is composed of a fluid impermeable material.

25. The device of claim 18 wherein the plurality of pores are perforations.

26. The device of claims 1-25 wherein the interior space is filled with compounds intended to stimulate bone growth.

27. The device of claims 1-25 wherein the material of the band or hoop at least partially includes at least one of the following: compounds, chemicals, hormones, pharmaceuticals, viruses, genetic materials and any combinations thereof intended to stimulate bone, cartilage or fibrous tissue growth.

28. A method for spinal disc stabilization wherein the surgeon uses the device of claims 1-25, around or within the annulus of a mammalian disc.

29. A method for spinal disc stabilization wherein the surgeon uses the device of claims 1-25, around or within the annulus of a mammalian disc, wherein the interior space of the band or hoop is filled with fill material.

30. A method for spinal disc stabilization wherein the surgeon uses the device of claims 1-25, around or within the annulus of a mammalian disc wherein the interior of the band or hoop is filled with a naturally occurring or artificial compound for the purpose of replacing the disc nucleus.

31. The method of claim 29 wherein the said fill material is a bioceramic compound.

32. The method of claim 29 wherein the said fill material is a bioceramic compound or bone graft combined with a bone growth stimulating chemical, wherein the growth stimulating chemical such as bone morphogenetic protein or other autogenous or allogenetic proteins.

33. The method of claim 29 wherein the said fill material is combined with a virus wherein the virus is constructed and arranged to stimulate bone formation.

34. The method of claim 29 wherein the said fill material is subjected to electrical energy stimulation.

35. A device for use in stabilizing a spinal motion segment comprising:

a generally hollow, flexible tubular member sized to fit into a hollowed region of an intervertebral space, the tubular member defining an interior space, the interior space extending from a first end to a second end, at least one end defining an opening, the opening in fluid communication with the interior space, the tubular member constructed and arranged to expand from a reduced state to an expanded state by the

introduction of fill material into the interior space, the tubular member including at least one fill opening through which the fill material may be introduced into the interior space, the at least one fill opening constructed and arranged to prevent egress of the fill material from the interior space.

36. The device of claim 35 wherein the flexible tubular member further comprises a plurality of pores, the plurality of pores being sized to allow ingress and egress of liquids, solutions, small particle suspensions and ingrowth of bony trabeculae or fibrous elements into and through the device when the device is positioned in a hollowed region of an intervertebral space, the plurality of pores being sized to retain the fill material within the interior space of the tubular member.

37. The device of claim 36 wherein each of the plurality of pores having a first diameter of about 0.25 mm to about 5 mm.

38. The device of claim 37 wherein the at least one fill opening comprises at least one of the plurality of pores.

39. The device of claim 37 wherein the fill opening has a predetermined diameter, the predetermined diameter of the fill opening being larger than the first diameter of any of the plurality of pores.

39. The device of claim 35 wherein the hollowed region of an intervertebral space is defined by adjacent vertebrae.

40. The device of claim 35 wherein the hollowed region of an intervertebral space is defined by a bored out region of a vertebra, the device being inserted into the bored out region of the vertebra.

41. The device of claim 35 wherein the hollowed region of an intervertebral space is defined by a bored out region of a disk, the device being inserted within the bored out region of the disk in the reduced state.

42. The device of claim 39 wherein in the expanded state the opening of the at least one end being immediately adjacent to at least one of the adjacent vertebrae.

43. The device of claim 35 wherein the first end defines a top opening and the second end defines a top opening, the top opening and the bottom opening each being immediately adjacent to surrounding vertebral tissue.

44. The device of claim 36 wherein the tubular member is composed of a polymeric material.

45. The device of claim 36 wherein the tubular member is composed of a woven material, wherein the woven material is comprised of at least one fiber.

46. The device of claim 45 wherein the at least one fiber is constructed at least partially from a shape-memory material.

47. The device of claim 46 wherein the shape-memory material is NITINOL.

48. The device of claim 36 wherein the tubular member is composed of a fluid impermeable material.

49. The device of claim 48 wherein the plurality of pores are perforations.

50. The device of claim 45 further comprising at least one longitudinally oriented support member.

51. The device of claim 50 wherein the longitudinally oriented support member is constructed of the at least one fiber.

52. The device of claim 45 further comprising at least one latitudinally oriented support member.

53. The device of claim 52, the at least one latitudinally oriented support member encircling the opening of the at least one end.

54. The device of claim 53 wherein the at least one latitudinally oriented support member is perpendicular relative to a longitudinally oriented support member when the device is in the expanded state.

55. The device of claim 38 wherein a fill insertion tool is inserted at least one of the plurality of pores, the at least one of the plurality of pores being opened from the first diameter to a second diameter, the second diameter being sized to allow the fill insertion tool to pass into the interior space of the device.

56. The device of claim 55 wherein the second diameter of the at least one of the plurality of the pores is at least as large as a diameter of the shaft of the fill insertion tool.

57. The device of claim 45 wherein the tubular member further comprises an inner wall and an outer wall, the inner wall and the outer wall being continuous with one another, the inner wall and the outer wall defining a space therebetween.

58. The device of claim 57 wherein at least one latitudinally oriented member is positioned within the space defined by the inner wall and the outer wall, the at least one latitudinally oriented member supporting the at least one fiber.

59. The device of claim 35 further comprising a delivery tube, the delivery tube defining a storage chamber, the storage chamber sized to accommodate passage of the

tubular member in the reduced state from within the storage chamber into the hollowed region of an intervertebral space.

ANNULUS-REINFORCING BAND

ABSTRACT OF THE DISCLOSURE

A pliable band or hoop that is flexible to normal handling, but cannot stretch circumferentially once it has reached the limits of its circumferential length. The band may have a structural portal to be used for filling, or it may simply be constructed of a fabric-like material that allows a fill tube to perforate its walls to allow for filling. In the latter case, the perforated wall tends to self-seal once the fill tube is withdrawn. The band may be flat or tubular in cross-section. However, unlike a balloon, the band does not require either a bottom or a top, as we found that a top and bottom are unnecessary when using a band or hoop to enclose material injected into a reamed out intervertebral space.

FIG. 4

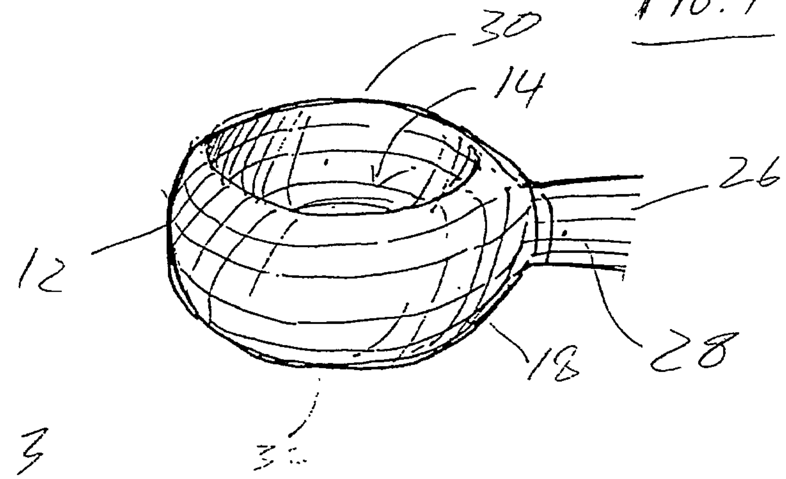
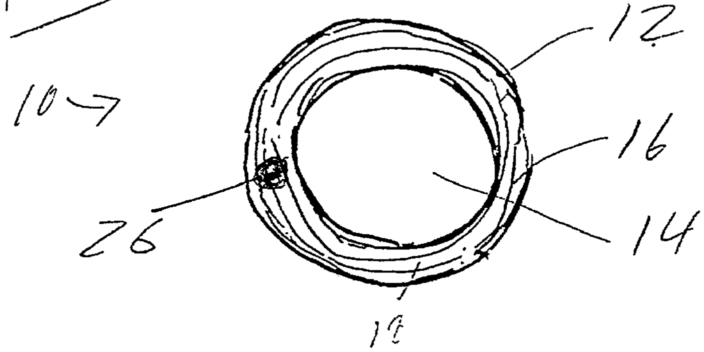


FIG. 3



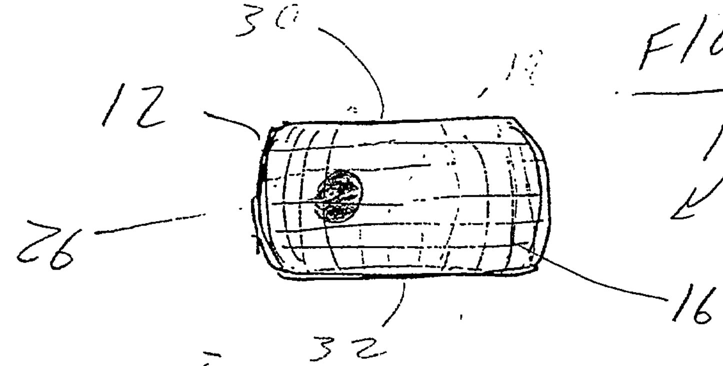


FIG. 2

FIG. 1

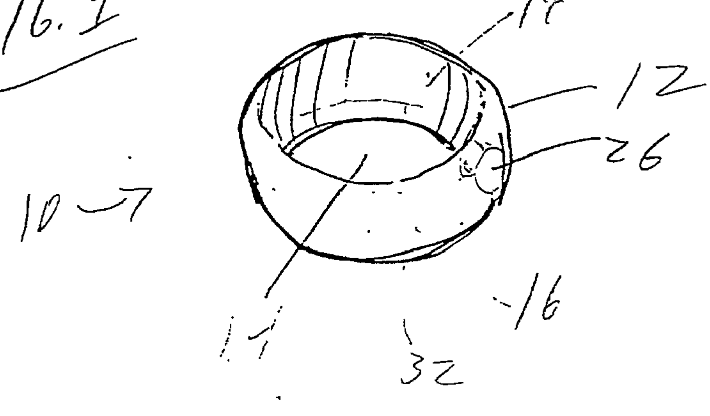


FIG. 5

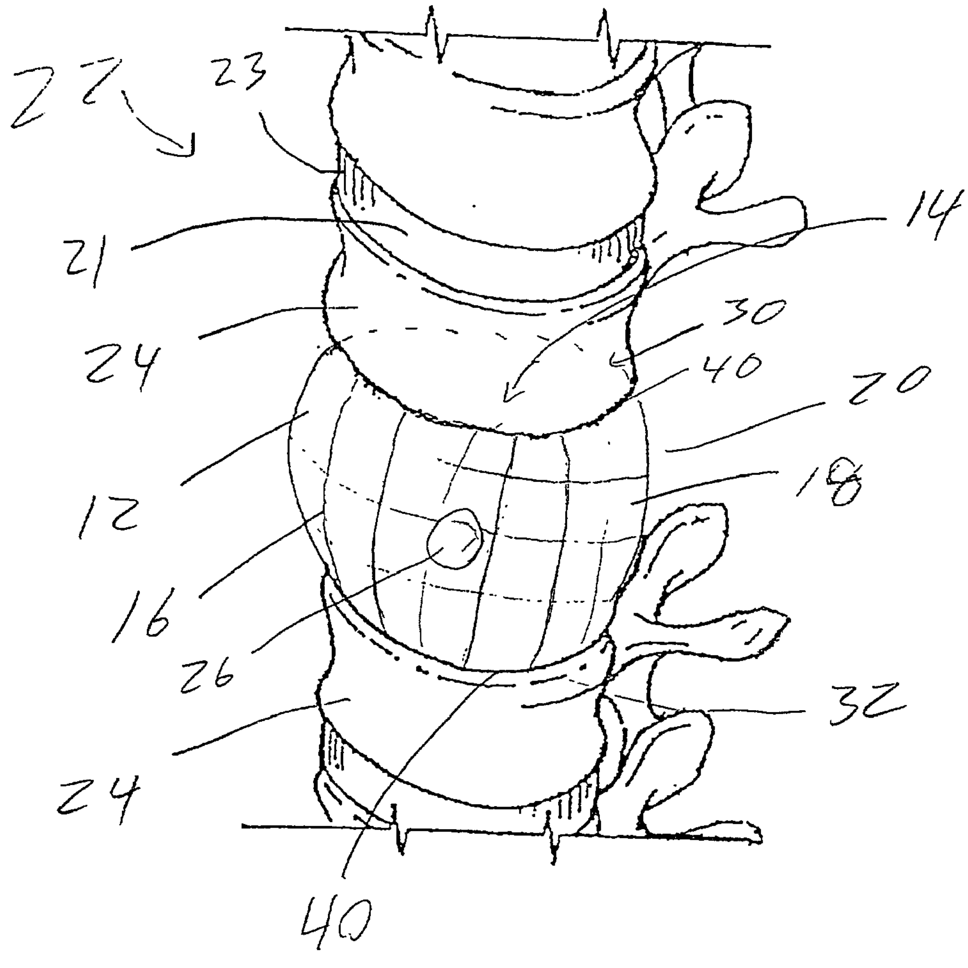


FIG. 6

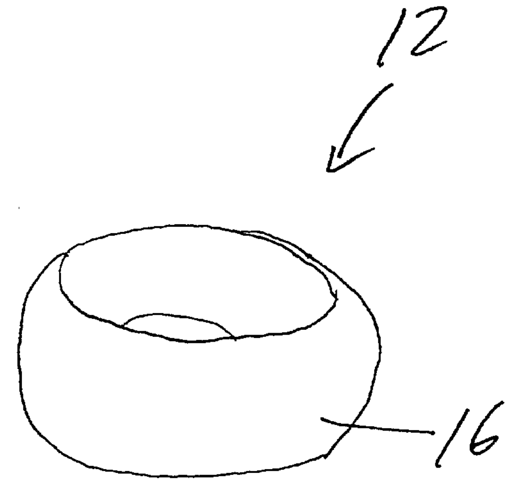


FIG. 7

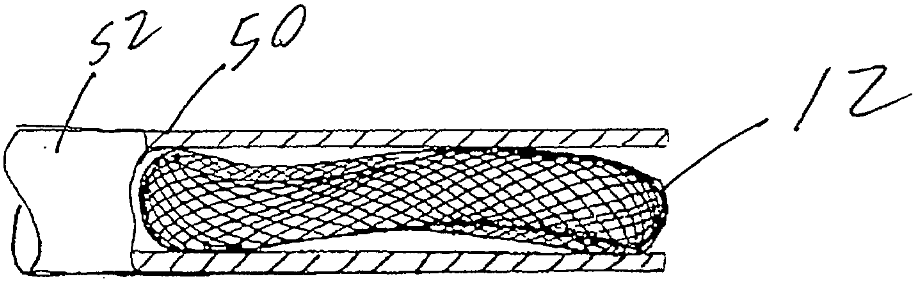
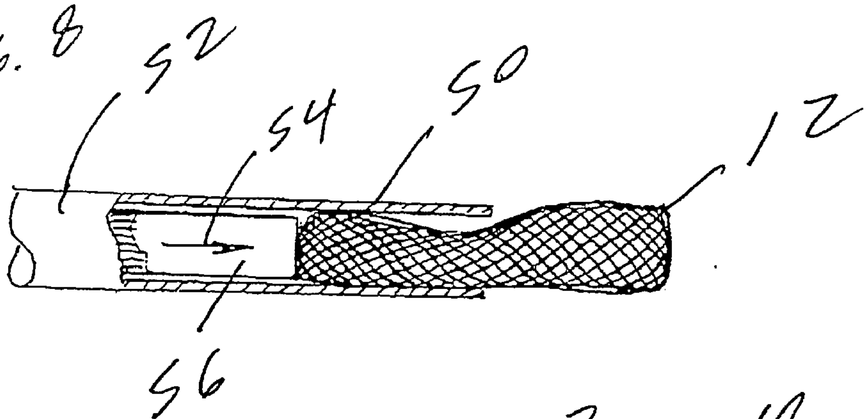


FIG. 8



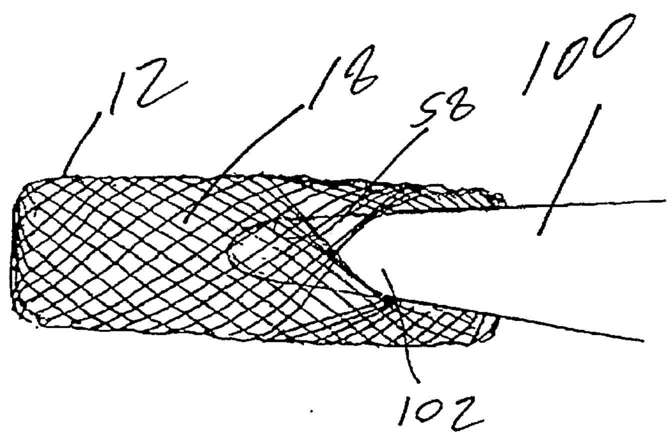


FIG. 22

FIG. 9

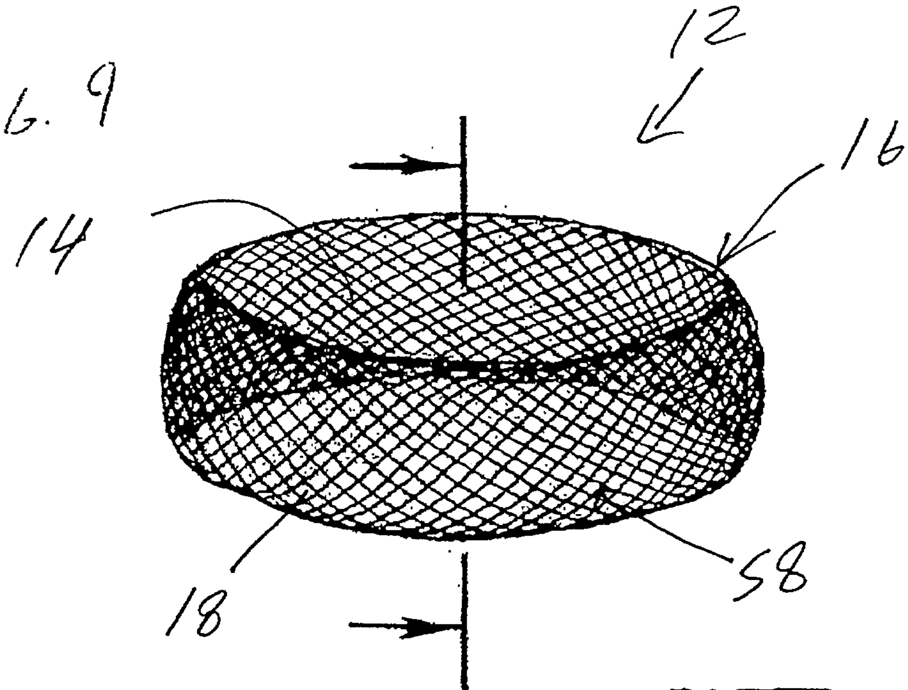


FIG. 10

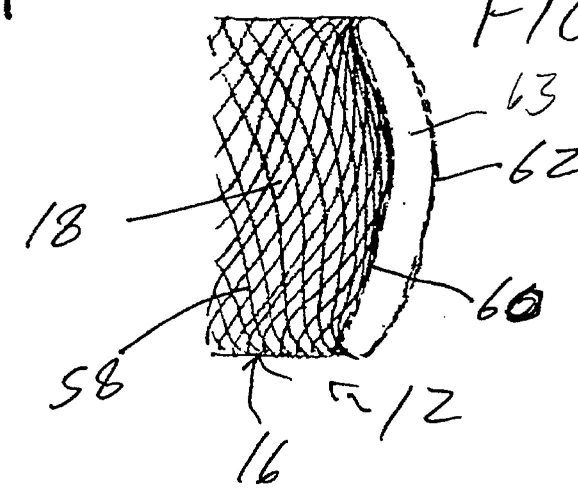


FIG. 11

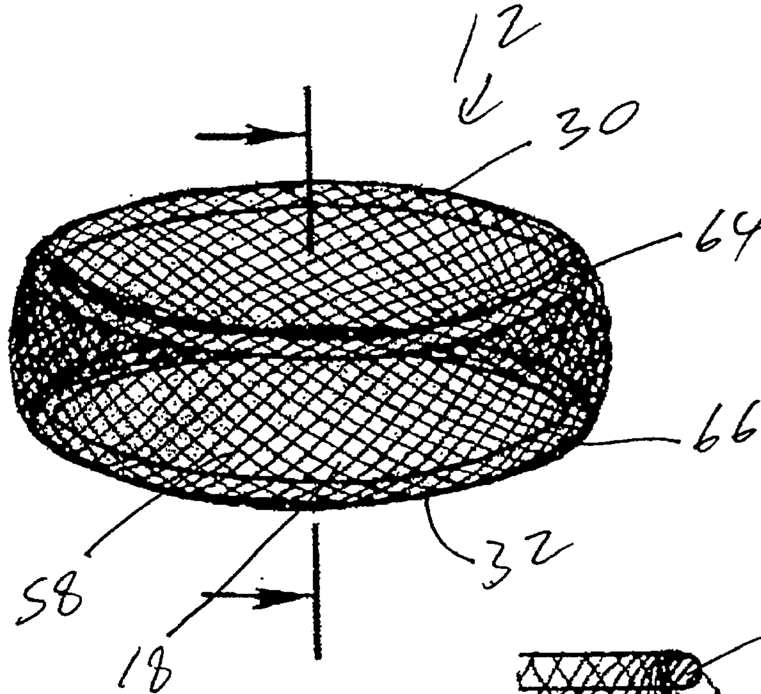


FIG. 12

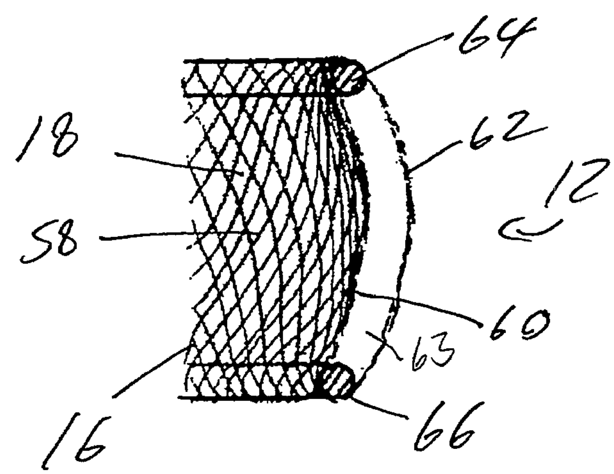


FIG. 13

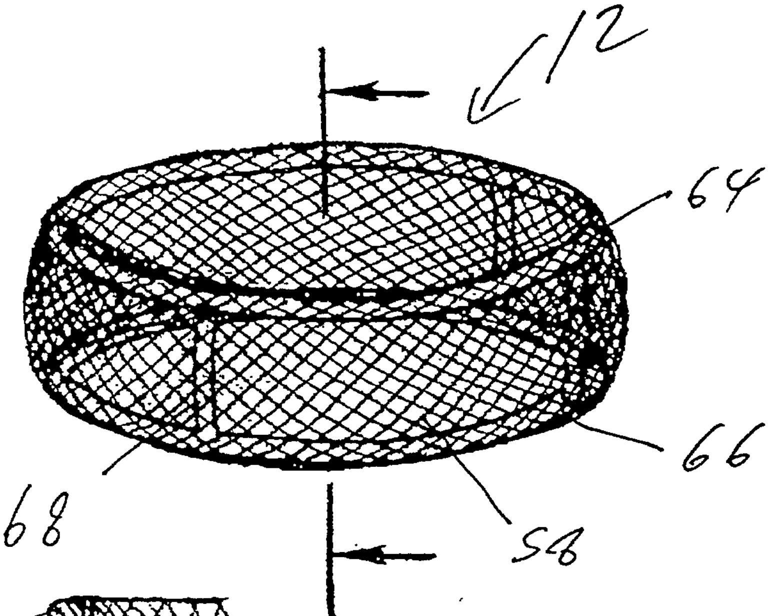
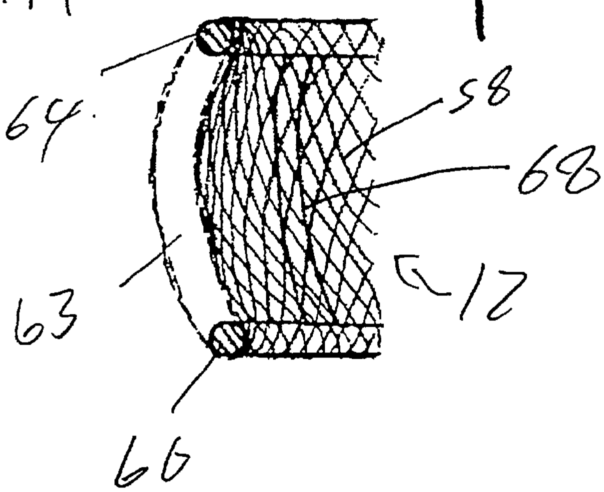


FIG. 14



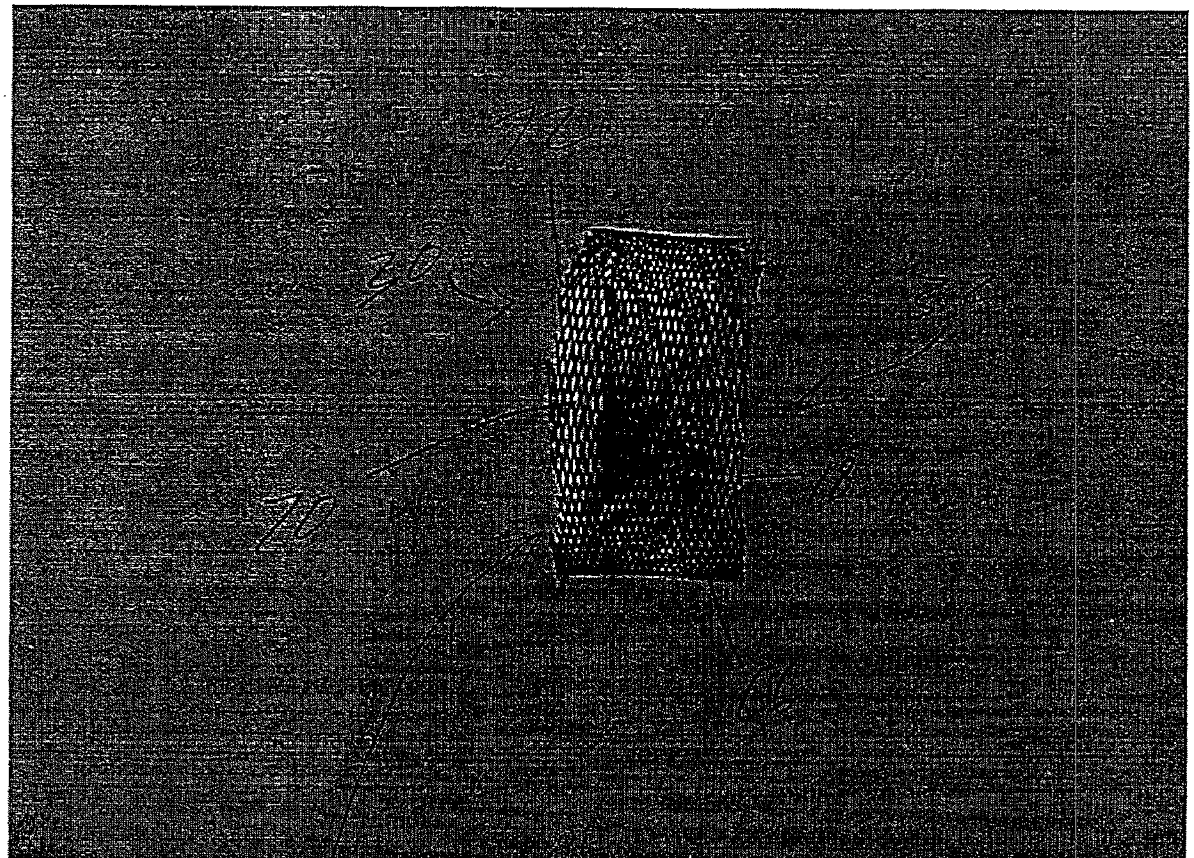


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FIG. 15

FIG. 16

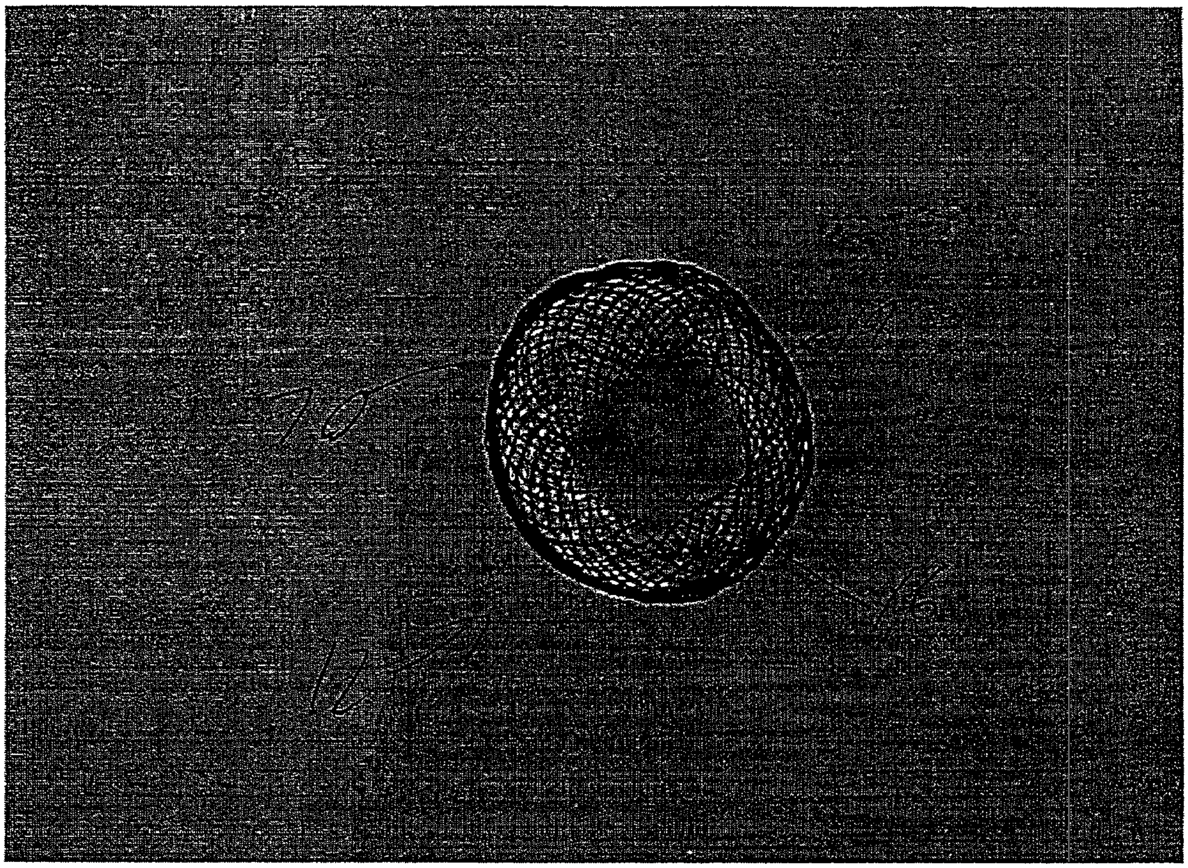

FIG. 17

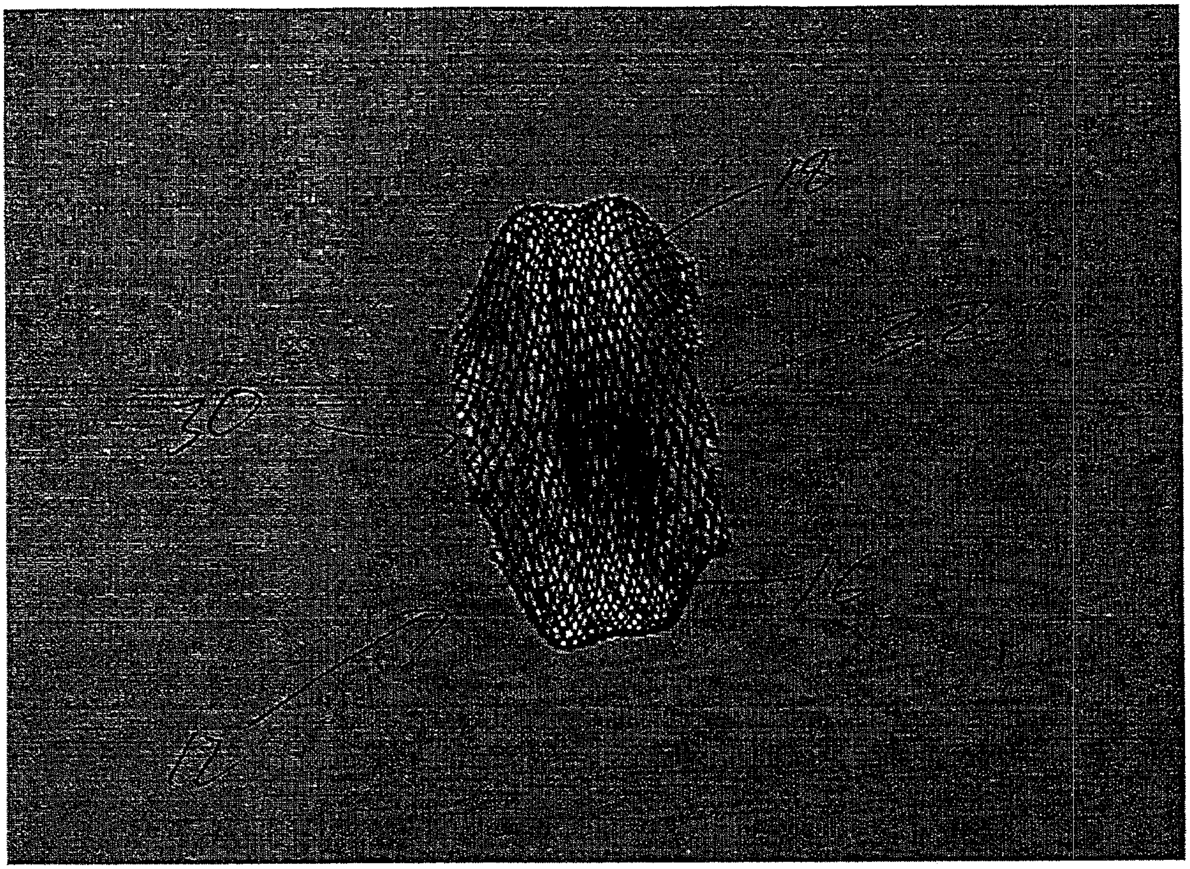

FIG. 18

FIG. 19

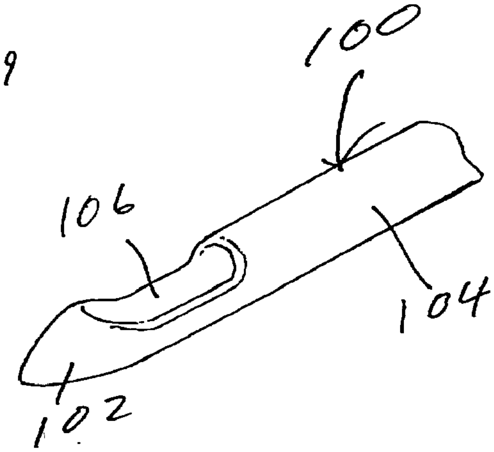

FIG. 20

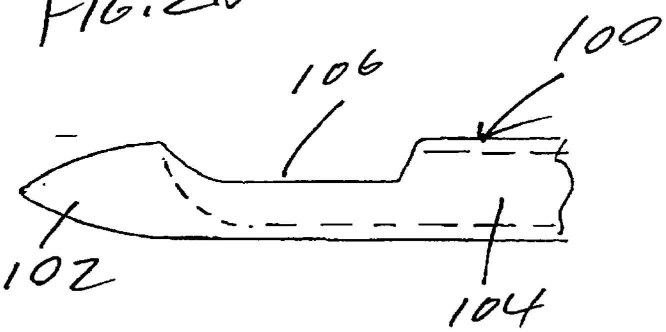

FIG. 21

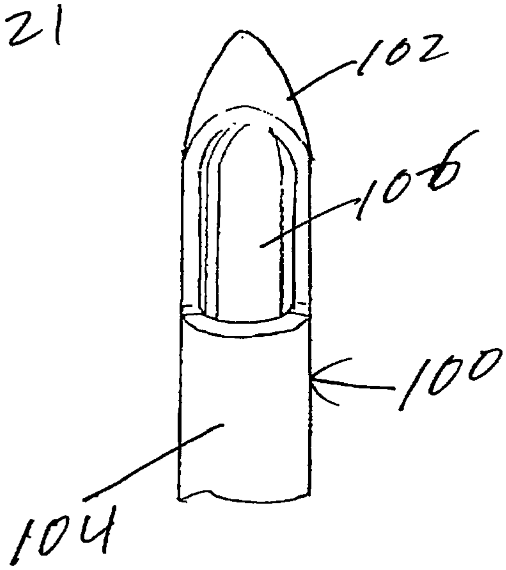

FIG. 23